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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/817,003	03/22/2001	David M. Sabatini	50347/002004	5682
21559 CLARK & ELI	7590 12/30/200 BING LLP	EXAMINER		
101 FEDERAL STREET			POPA, ILEANA	
BOSTON, MA 02110			ART UNIT	PAPER NUMBER
			1633	
			NOTIFICATION DATE	DELIVERY MODE
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# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail  $\,$  address(es):

patentadministrator@clarkelbing.com

# Application No. Applicant(s) 09/817.003 SABATINI, DAVID M. Office Action Summary Examiner Art Unit ILEANA POPA 1633 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 02 October 2009. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 160-177 and 237-272 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 160-177 and 237-272 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner, Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) ☐ All b) ☐ Some \* c) ☐ None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)

Paper No(s)/Mail Date

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (PTO/SE/68)

Paper No(s)/Mail Date. \_\_\_\_

6) Other:

5) Notice of Informal Patent Application

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#### DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/02/2009 has been entered.

Claims 1-159 and 178-236 have been cancelled. Claim 272 is new.

Claims 160-177 and 237-272 are pending and under examination.

### Note: Change of Examiner

The Examiner of record is now Ileana Popa, Art Unit 1633. Therefore, future correspondence should reflect such changes. Also, at the end of the Action is the information regarding the SPE and the Art Unit.

 Upon further consideration, the following rejections are withdrawn in favor of new rejections which use Palsson's teachings under 35 U.S.C. 102(b):

The rejection of claims 160-169, 172-175, 178-248, 251, 253-254, 257, 259-260, 263, 265-266, 269 and 271 under 35 U.S.C. 102(a) and (e) as being anticipated by Palsson (US 5811274, 1998);

The rejection of claims 170-171, 176-177, 249-250, 252, 255-256, 258, 261-262, 264, 267-268, 270 under 35 U.S.C. 103(a) as being unpatentable over Palsson (US

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5811274, 1998) in view of Montgomery et al. (PNAS 95(26): 15502-7, 1998) and Fire et al. (US 6506559, 2003).

#### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- Claims 160-163, 166, 169, 172, 173, 175, 241, 242, 244-248, 251, 253, 254, 257,
   259, 260, 263, 265, 266, 269 and 271 rejected under 35 U.S.C. 102(b) as being anticipated by Palsson (WO 96/17948, Applicant's IDS).

Palsson teaches a reverse transfection surface which is an array comprising a support suitable for culturing cells which does not contain wells, the support comprising nucleic acids deposited at a plurality of distinct locations (i.e., discrete) and plating dispersed eukaryotic cells on top of the nucleic acids (i.e., the plurality of locations comprise eukaryotic cells and nucleic acids in discrete locations). The cells become transfected with the nucleic acids after culturing the array for a suitable period of time (claims 160, 172, 246, 247, 253, 259, 265 and 271) (Abstract, p. 5, line 29 through p. 6, line 10; p. 8, lines 1-15, p. 10, lines 1-5; p. 11, lines 22-25; p. 12, lines 26-32; p. 14, line 25 through p, 15, line4; p. 17, lines 26-28; Example III, Fig. 4-6). The nucleic acids could be plasmids (claims 161-163, 166, 173, 248, 254, 260 and 266) or RNAs (claim 169), the nucleic acids further comprise carriers such as liposomes (i.e., lipids) (claims

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175, 242, 251, 257, 263 and 269), the nucleic acids could be non-covalently bound to the support via antibodies, adhesion molecules or polycations such as polylysine (claims 173, 241, 244 and 245) (p. 8, lines 20-25; p. 9, lines 5-7; p. 12, lines 24-30). Since Palsson teaches all claim limitations, the claimed invention is anticipated by the above cited art.

# Claim Rejections - 35 USC § 103

- 5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- Claims 160-166, 169, 172, 173, 175, 241-248, 251, 253, 254, 257, 259, 260, 263,
   265, 266, 269 and 271 are rejected under 35 U.S.C. 103(a) as being unpatentable over

  Palsson.

The teachings of Palsson are applied as above for claims 160-164, 166, 169, 172, 173, 175, 241, 242, 244-248, 251, 253, 254, 257, 259, 260, 263, 265, 266, 269 and 271. Although Palsson et al. teaches adhesion molecules, he does not specifically teach fibronectin (claim 243). However, fibronectin was well-known in the prior art as an adhesion molecule. Therefore, it would have been obvious to one of skill in the art, at the time the invention was made, to modify Palsson's transfection surface by using fibronectin as an adhesion molecule to achieve the predictable result of obtaining a

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device suitable for transfection. Palsson does not specifically teach that the nucleic acids encode a polypeptide (claim 164). However, using such to express polypeptides into cells was routine in the prior art. Therefore, it would have been obvious to one of skill in the art, at the time the invention was made to include nucleic acids encoding polypeptides into Palsson's transfection surface to achieve the predictable result of obtaining a device suitable for expressing polypeptides of interest into cells. Palsson does not specifically teach the cell density recited in claim 165. However, absent evidence of unexpected results, it would have been obvious to one of skill in the art to vary the cell density with the purpose of optimizing the transfection results. Again, absent evidence to the contrary, it is generally not inventive to discover the optimal working conditions of a prior art method, such conditions can be identified by routine experimentation (see MPEP 2144.05 IR-51).

Thus, the claimed invention was prima facie obvious at the time the invention was made

Claims 160-164, 166-177, 237-242 and 244-271 are rejected under 35 U.S.C.
 103(a) as being unpatentable over Palsson, in view of both Taylor et al. (U.S. patent No. 6,103,479, of record) and Fire (U.S. Patent No. 6,506,559, of record).

The teachings of Palsson are applied as above for claims 160-164, 166, 169, 172, 173, 175, 241, 242, 244-248, 251, 253, 254, 257, 259, 260, 263, 265, 266, 269 and 271.

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Although Palsson teaches that the transfection surface can be made with any apparatus which allows nucleic acid deposition on the support (p. 20, lines 4 and 5), he does not teach a microarrayer, wherein the use the microarray results in an array arranged in rows and columns and comprising different nucleic acids at different locations (claims 168, 272, 174 and 237-240). However, doing such is suggested by the prior art. For example, Taylor et al. teach high throughput screening (HTS) screening of nucleic by using arrays comprising tens of thousands nucleic acid discrete spots, wherein the arrays are made by using a microarrayer and wherein the location of the spot in the array provides the address for later reference to each nucleic acid spot; they also teach HTS of the physiological responses of cells to biologically active compounds (column 1, lines 47-56, column 6, lines 40-52). It would have been obvious to one of skill in the art, at the time the invention was made, to modify Palsson according to the teachings of Taylor et al. to obtain the predictable result of obtaining a transfection surface suitable for HTS of cellular response to diverse biologically active factors encoded by nucleic acids. With respect to the limitation recited in claim 167, it would have been obvious to one of skill in the art to spot at least two different nucleic acids at the same discrete location when transfection with more than one nucleic acid was needed.

Palsson and Taylor et al. do not teach siRNA (claims 170, 171, 176, 177, 249, 250, 252, 255, 256, 258, 161, 262, 264, 267, 268 and 270). However, doing such is suggested by the prior art. For example, Fire et al. teach screening siRNA in a HTS setting (column 12, lines 46-61). It would have been obvious to one of skill in the art, at

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the time the invention was made, to modify transfection surface of Palsson and Taylor et al. by using siRNA achieve the predictable result of obtaining a device suitable for screening siRNA in a HTS setting.

Thus, the claimed invention was *prima facie* obvious at the time the invention was made.

8. No claim is allowed. No claim is free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILEANA POPA whose telephone number is (571)272-5546. The examiner can normally be reached on 9:00 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ileana Popa/ Primary Examiner, Art Unit 1633